UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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James J. Sales
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In re: Patent Term Extension Application for U.S. Patent No. 5,929,304

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REQUIREMENT FOR INFORMATION PURSUANT TO 37 CFR 1.750

This is in response to the application for patent term extension under 35 U.S.C. § 156, filed June 26, 2012, by Virginia Tech Intellectual Properties, Inc. An extension of 1,291 days is requested.

Pursuant to 37 CFR 1.750, applicant is required to submit the following to the Office:

(1) Evidence that Virginia Tech Intellectual Properties Inc. is authorized by the co-owner of the patent, Croptech Development Corporation, to seek extension of U.S. Patent No. 5,929,304.

(2) Evidence that Virginia Tech Intellectual Properties Inc. and Croptech Development Corporation were authorized by Protalix Ltd.[1], the marketing applicant before the Food and Drug Administration, to rely upon the premarket activities of Protalix Ltd. in seeking extension of U.S. Patent No. 5,929,304 (the '304 patent).

First, the language of 35 U.S.C. 156(d)(1) requires that the "owner of record of the patent or its agent" makes the application for patent term extension. When a patent is owned by more than one entity, the entities must act together as a composite entity in patent matters before the Office, see MPEP 301 IV. Here, only one patent owner has made the application for patent term extension. Thus, the other owner, Croptech Development Corporation must provide authorization to Virginia Tech Intellectual Properties, Inc. to seek extension of the term of the '304 patent based on the regulatory review of NDA 22-458 for the human drug product ELELYSO™.

Second, the above-identified application for patent term extension relies upon the regulatory review for the human drug product ELELYSO™ (taliglucerase alfa). Exhibit G of the present application shows that the holder of New Drug Application (NDA) No. 22-458, ELELYSO™ (taliglucerase alfa) is Protalix Ltd. An application for patent term extension for U. S. Patent No. 7,951,557 has already been filed by Protalix, Ltd. based upon the same regulatory review period, requesting an extension of 336 days.

The right to a patent term extension pursuant to 35 U.S.C. § 156 is granted to patent owners to compensate for lost patent term while the patent owner, or his agent, sought premarket approval from a regulatory agency. See Manual of Patent Examining Procedure, § 2750. Section 156(d)(1)(D) of Title 35 of the United States Code requires a description of the activities undertaken by the applicant (i.e., the patent owner or its agent) during the regulatory review period, and specifies in § 156(d)(2)(B)(i) that the lack of due diligence by the applicant during the

[1]NDA No. 22-458 is now owned by Pfizer Inc. Thus, authorization from Protalix Ltd. to rely on their regulatory review activities is necessary and an explanation of the agency relationship between the patent owners of the '304 patent and the current NDA owner is needed, or an authorization from the current NDA holder to rely on the regulatory review activities of Protalix, Inc. is necessary.

regulatory review period may be taken into account. Given these statutory requirements, the Office has held that in order to be eligible for patent term extension, the patent owner or its agent must have undertaken the activities that led to the regulatory approval. If a patent owner has not been involved in the regulatory process, either directly or indirectly, that patent owner has not lost any effective patent life since it never invested time and resources necessary to obtain approval for commercial marketing or use. See Decision Denying Application, (United States Patent and Trademark Office Deputy Assistant Comm'r for Patent Policy and Projects Apr. 3, 1995) (concerning patent term extension application for United States Patent No. 4,631,286); aff'd, Hoechst-Roussel Pharms., Inc. v. Lehman, No. 95-650-A (E.D. Va. Oct. 27, 1995); aff'd, 109 F.3d 756, 759, 42 U.S.P.Q.2d 1220, 1223 (Fed. Cir. 1997) (Newman, C.J., concurring) (affirming on other grounds, but Judge Newman concurring in the judgment on this basis). See also Amendment to Rules for Extension of Patent Term, 60 Fed. Reg. 25615, 25616 (May 12, 1995).

The regulatory review period of ELELYSO™ (taliglucerase alfa) can be used as a basis for extension of only one patent. See 35 U.S.C. § 156(c)(4) and 37 CFR 1.785. Since both U.S. Patent No. 7,951,557, owned by Protalix, Ltd. and U.S. Patent No. 5,929,304, owned by Virginia Tech Intellectual Properties Inc. and Croptech Development Corporation, are relying upon the premarket activities of Protalix Inc. to support applications for patent term extension, the Office now requires Virginia Tech Intellectual Properties Inc. and Croptech Development Corporation to provide evidence, as set forth above, of its eligibility to apply for extension of the term of the '304 patent under 35 U.S.C. § 156, by demonstrating their agency relationship with the NDA holder, namely Protalix, Ltd./Pfizer.

Applicant is given two months to reply to this requirement. Extension of time are available under 37 CFR 1.136.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
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Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
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Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
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Attention: Beverly Friedman

RE: ELELYSO™ (taliglucerase alfa)
Docket No.: FDA-2012-E